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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1649

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/787,194 | ENDOU ET AL. | |
| | Examiner | Art Unit | |
| | John D. Ulm | 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/15/01, 1/21/03, 3/05/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- 1) Claims 1 to 7 are pending in the instant application.

Election/Restrictions

2) Applicant's election of invention I, drawn to an organic ion transporter polypeptide, in the reply filed on 14 January, 2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3) Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements. These claims encompass subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 encompasses any protein that might be encompassed by the limitation "cerebral type organic anion transporter OAT3". Claim 2 is essentially as broad as claim 1 since the phrase an "amino acid sequence with such a modification of the amino

Art Unit: 1649

acid sequence represented by SQ ID No. 2 or 4 as deletion of a part of the amino acid sequence, or substitution or addition with other amino acids” allows one to change every amino acid in SEQ ID NO:2 or SEQ ID NO:4 so long as the protein remains a “cerebral type organic anion transporter”. As such, these are single means claims. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a)

In addition, the text in the first full paragraph on page 4 of the instant specification states that “[t]he inventive organic anion transporter OAT3 is a transporter with a wide range of substrate selectivity and transports organic anions with different chemical structures”, thereby functionally defining the term “cerebral type organic anion transporter OAT3”. However, the only functional “OAT3” proteins that are described in the specification comprise either the entire amino acid sequence presented in either SEQ ID NO:2 or SEQ ID NO:4. The instant specification does not describe any other

“OAT3” protein in sufficient detail to demonstrate possession thereof as of the filing of the instant application.

In the precedential opinion in *Ex parte Kubin*, 83 USPQ2d 1410 (BPAI 2007), the Board of Patent Appeals and Interferences determined that the subject matter of a claim (claim 73) encompassing “a genus of polynucleotides encoding polypeptides ‘at least 80% identical to amino acids 22-221 of SEQ ID NO:2’ which bind to CD48” was not adequately described by a specification disclosing the sequences of “two nucleic acids falling within the scope of” the claim “and three fusion proteins whose” encoding “nucleotide sequences would fall within the scope of” that claim. As stated in that opinion, “[n]one of these sequences varies amino acids 22-221 of NAIL, and thus these sequences are not representative of the genus” claimed. The board held that:

“Appellants also have described how to make and test other sequences within claim 73 sufficiently to satisfy the enablement requirement. However, they have not described what domains of those sequences are correlated with the required binding to CD48, and thus have not described which of NAIL’s amino acids can be varied and still maintain binding. Thus, under *Lilly*’ (*Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406) “and its progeny, their Specification would not have shown possession of a sufficient number of sequences falling within their potentially large genus to establish possession of their claimed genus. *Cf. Enzo*, 323 F.3d at 964, 63 USPQ2d at 1612 (‘if the functional characteristic of ...binding to [CD48] were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed,’ the written description requirement may be met).

Without a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (‘definition by function...does not suffice to define the genus because it is only an indication of what gene does, rather than what it is’)

In the instant case, claims 1 and 2 recite the functional limitation required by the term “organic anion transporter *OAT3*” in the complete absence of the recitation of any of those structural features that must be present to provide that recited functionality.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4) Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4.1) Claims 1 and 2 are vague and indefinite in so far as they employ the term “organic anion transporter *OAT3*” as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of an “organic anion transporter *OAT3*” an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. For example, it is unclear how the phrase “an organic anion transporter *OAT3* comprising the amino acid sequence of SEQ ID NO:2” differs in scope from “an organic anion transporter comprising the amino acid sequence of SEQ ID NO:2”, which is unambiguous because only a function and a corresponding structure are recited.

4.2) Claim 2 is vague and indefinite because the metes and bounds of the phrase “an amino acid sequence with such a modification of the amino acid sequence represented by SQ ID No. 2 or 4 as deletion of a part of the amino acid sequence, or substitution or addition with other amino acids” are undeterminable.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5) Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims encompass a protein as it occurs in nature and, therefore, is neither new nor the invention of Applicant. To avoid such a rejection, the claims should recite an inventive concept that reflects the hand of man, such as requiring the protein to be “isolated”, as taught in the third paragraph on page 1 of the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6) Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by the Beier et al. patent publication (WO 97/42321, 13 Nov. 1997, cited by Applicant). These claims encompass the protein that was described in SEQ ID NO:4 of Beier et al., which is 94.7% identical to SEQ ID NO:2 of the instant application.

7) Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by the Sekine et al. publication (J. Biol. Chem. 272(30):18526-18529, 25 Jun. 1997,

cited by Applicant). Because the instant specification fails to identify those structural or functional features that materially distinguish a “cerebral organic anion transporter OAT3” from any other organic ion transporter expressed in a brain, these claims appear to encompass the organic ion transporter protein described in Figure 2 on page 18528 of Sekine et al. The text in the first full paragraph on that page discloses that the transporter protein described therein is expressed in rat brain.

Allowable Subject Matter

8) The prior art of record did not disclose or suggest an isolated protein comprising the entire amino acid sequence presented in SEQ ID NO:2 or 4 of the instant application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/
Primary Examiner, Art Unit 1649